

## REMARKS/ARGUMENTS

No new matter has been added by the drawings in additional sheets 9, 10, and 11, or by the discussion of these drawings in new paragraphs 0179.1 through 0179.12. Sheets 9, 10, and 11 are being submitted to illustrate *known* ways for attachment of sutures and surgical needles, respectively with shrink wrapping, channel wrapping, and eyelet threading. Therefore, the Examiner is respectfully requested to enter sheets 9, 10, and 11, and also to enter paragraphs 0179.1 through 0179.12.

No new matter has been added by any of the above amendments to the claims, and therefore, the Examiner is respectfully requested to enter the amendments.

Independent claims 1, 17, 18, 21, and 32, 33, and 36 have been amended to indicate that the needle diameter is "at the needle's thickest part", in order to avoid any ambiguity as to which part of the needle is intended. Support is at applicants' Figures 13A, 13B, 13C, and 13D as filed, from which can be seen that the diameter of the needle is clearly designated as the thickest part of the needle.

Each of originally dependent claims 17, 18, and 21 (each of which depended back to dependent claim 12, which depends back to independent claim 1) has been rewritten to be an independent claim, incorporating all of the limitations of original claims 12 and 1.

Also, claim 32 has been amended so that the ratio is "2:1 or less" instead of "3:1 or less" in order to differentiate from dependent claim 2. Support for "2:1 or less" is at paragraph 0185 of applicants' specification.

New method claims 37 – 54 correspond respectively to original product claims 1 – 16, 32, and 33. Support for a method of suturing tissue is at paragraphs 0181 through 0206 of applicants' specification.

### *I. Discussion of objections to drawings.*

The Examiner cited 37 CFR 1.83(a) and noted that the drawings are to show every feature of the invention specified in the claims. The Examiner made two objections.

**Additional Drawing Sheets:**

The attached additional sheets 9, 10, and 11 of drawings show suture/surgical needle attachments respectively by shrink wrapping (sheet 9 with Figs. 14A, 14B, 14C, and 14D), channel wrapping (sheet 10 with Figs. 15A, 15B, 15C, and 15D), and eyelet threading (sheet 11 with Figs. 16A, 16B, 16C, and 16D).

Attachment: Additional drawing sheets 9, 10, and 11

For the first objection, the Examiner stated that the drawings must show the attachment of the suture and surgical needle by shrink wrapping, channel wrapping, and eyelet threading.

As discussed above, the attached additional sheets 9, 10, and 11 of drawings show suture/surgical needle attachment respectively by shrink wrapping (attached additional sheet 9 with Figs. 14A, 14B, 14C, and 14D), channel wrapping (attached additional sheet 10 with Figs. 15A, 15B, 15C, and 15D), and eyelet threading (attached additional sheet 11 with Figs. 16A, 16B, 16C, and 16D).

More specifically, for additional sheet 9, shown respectively in Figs. 14A, 14B, 14C, and 14D is shrink wrapping SW1, SW2, SW3, and SW 4, illustrated in cutaway and disposed about each respective needle/suture N1/S1, N2/S2, N3/S3, and N4/S4, where the end of each suture S1, S2, S3, and S4 is disposed in the respective bore holes H1, H2, H3, and H4 at the respective ends the needles N1, N2, N3, and N4.

Also, for additional sheet 10, shown respectively in Figs. 15A, 15B, 15C, and 15D is channel wrapping CW1, CW2, CW3, and CW4, illustrated in cutaway and disposed about each respective needle/suture N1/S1, N2/S2, N3/S3, and N4/S4, where the end of each suture S1, S2, S3, and S4 is disposed in the respective channels C1, C2, C3, and C4 at the respective ends of the needles N1, N2, N3, and N4.

Also, for additional sheet 11, shown respectively in Figs. 16A, 16B, 16C, and 16D is eyelet threading for each respective needle/suture N1/S1, N2/S2, N3/S3, and N4/S4, where the end of each suture S1, S2, S3, and S4 is disposed in the respective eyelets E1, E2, E3, and E4 at the respective ends of the needles N1, N2, N3, and N4.

These additional sheets 9, 10, and 11 are being submitted to illustrate *well known* ways that sutures and surgical needles are attached, namely with shrink wrapping, channel wrapping, and eyelet threading. Also, appropriate amendments to the specification pages, reflecting the above comments vis-à-vis what is shown in additional sheets 9, 10, and 11, are being submitted as per new paragraphs 0179.1 through 0179.12.

Applicants are not claiming that they invented attachments of sutures and surgical needles, and as applicants noted in paragraph 0060 of their specification, various U.S. patents disclose various well known ways for attaching sutures and surgical needles.

Thus, no new matter is being added by the drawings or by the new paragraphs discussing the drawings, and therefore, the Examiner is respectfully requested to enter them.

Accordingly, the Examiner is respectfully requested to withdraw the objection that the drawings must show shrink-wrapping, channel wrapping, and eyelet threading, and respectfully requested to accept additional sheet 9 (Figs. 14A, 14B, 14C, and 14D), additional sheet 10 (Figs. 15A, 15B, 15C, and 15D), additional sheet 11 (Figs. 16A, 16B, 16C, and 16D), and new paragraphs 0179.1 through 0179.12.

For the second objection, the Examiner stated that the drawings must show that the underside of the overlapping barb is derived from part of the top side of the overlapped barb.

Applicants respectively traverse. This feature is already shown in Figures 12A, 12B, 12C, and 12D, all on drawing sheet 7. These figures are discussed in paragraphs 0170, 0171, 0172, and 0173 of applicants' specification.

Accordingly, the Examiner is respectfully requested to withdraw the objection in connection with a drawing to show the overlapping barb being derived from part of the top side of the overlapped barb.

***II. Discussion of rejection of claims 1, 2, 5 - 12, 14, 16, 23 - 33, and 36 under 35 USC §102(e) as being anticipated by, or in the alternative, obvious over either U.S. Patent No. 6,599,310 to Leung et al. or U.S. Published Patent Application No. 2004/0030354 to Leung et al. (in view of U.S. Patent No. 5,123,911 to Granger et al.).***

With regard to '310 and '354, both to Leung et al., the Examiner stated that the "figures show the proximal end of the needle [*sic*, is] about the same diameter of the suture".

Also, the Examiner stated that lines 13 - 21 of col. 7 of '911 to Granger et al. disclose "it was known to attach sutures of equal diameter to the suturing needle" and Fig. 12 of '911 to Granger et al. shows "the diameter of the needle shank portion 12 is smaller than the diameter of the suture."

Additionally, the Examiner stated that applicants' "claimed needle diameter could be the diameter of the needle at the sharpened tip, which would be smaller in diameter than the suture material." In connection therewith, applicants respectfully point out, as can be clearly seen in their Figures 13A, 13B, 13C, and 13D as filed, the diameter of the needle is clearly designated as the thickest part of the needle, and note that the rejected independent claims have been amended to indicate that the needle diameter is "at the needle's thickest part".

First, it is respectfully pointed out that if the Examiner meant to combine one or both of Leung et al. with Granger et al., in order to assert an obviousness rejection, then the Examiner should have cited 35 USC §103(a) because 35 USC §102(e) relates only to anticipation.

However, applicants respectfully point out that under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

At the time that the presently claimed invention was made, it and both of '310 to Leung et al. and '354 Leung et al., were owned by and also subject to an obligation of assignment to the same person, Quill Medical, Inc.

Accordingly, the Examiner is respectfully requested to remove the obviousness rejection based on one or both of Leung et al. in view of Granger et al.

Furthermore, as the Examiner should be aware, for a reference to be a reference under any subparagraph of §102, that reference, by *itself*, must teach each and every element of the claimed invention. That is not achieved by U.S. Patent No. 6,599,310 to Leung et al. by itself; that is not achieved by U.S. Published Patent Application No. 2004/0030354 to Leung et al. by itself.

Applicants respectfully point out that the specifically claimed ratio of the surgical needle diameter to the barbed suture diameter of about 3:1 or less is not in either '310 to Leung et al. or '354 Leung et al.

Accordingly, the Examiner is respectfully requested to remove the §102(e) rejection based on one or both of Leung et al.

Hence, remaining is only the rejection for obviousness solely in view of U.S. Patent No. 5,123,911 to Granger et al.

***Rejection of Claims 1, 2, 5 - 12, 14, 16, 32, and 33 for obviousness in view of '911 to Granger et al.***

The Examiner is respectfully reminded that, as specifically stated in paragraph 0181 of applicants' specification:

As is well known in the art, needle diameter for surgical needles used with conventional (i.e., unbarbed) sutures is considered unimportant, and often very thick surgical needles are used with thin conventional sutures such that the ratio of surgical needle diameter to conventional suture diameter is 4:1 or even higher, such as 4.43:1.

Summarily, '911 to Granger et al. is not relevant to barbed sutures.

In paragraph 60 of applicants' specification, applicants cited '911 to Granger et al. as mere background for illustrating attachment of sutures to surgical needles. Specifically, '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, but rather involves an apparatus for attaching conventional sutures to surgical needles. Thus, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 1, 2, 5 - 12, 14, 16, 32, and 33 with regard to U.S. Patent No. 5,123,911 to Granger et al.

***Rejection of Claims 23 - 31 for obviousness in view of '911 to Granger et al.***

Since each of dependent claims 24 - 31 depends back to claim 23, the limitations of claim 23, are incorporated by reference into each of dependent claims 24 - 31.

Claim 23 recites various limitations for the barbs of a barbed suture, namely:

the barbs have a configuration selected from the group consisting of (i) a barb cut angle  $\theta$  ranging from about 140 degrees to about 175 degrees, (ii) a barb cut depth with a ratio of the barb cut depth to the suture diameter ranging from about 0.2 to about 0.6, (iii) a barb cut length with a ratio of the barb cut length to the suture diameter ranging from about 0.6 to about 2, (iv) a barb cut distance with a ratio of the barb cut distance to the suture diameter ranging from about 1 to about 6, (v) a corrugated barb underside, (vi) an arcuate barb base, (vii) at least two sets of barbs with each set having a barb size different from the barb size of the other set, and (viii) combinations thereof.

As noted above, '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, but rather involves an apparatus for attaching conventional sutures to surgical needles. Thus, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter, and where the barbs have the various limitations as set out in claim 23.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 23 - 31 with regard to U.S. Patent No. 5,123,911 to Granger et al.

***III. Discussion of rejection of claims 1, 2, 5 - 8, 10 - 13, 15, 16, and 23 - 33 under 35 USC §102(e) as being anticipated by, or in the alternative, obvious over U.S. Patent No. 5,931,855 to Buncke (in view of U.S. Patent No. 5,123,911 to Granger et al.).***

First, it is respectfully pointed out that if the Examiner meant to combine Buncke with Granger et al. to assert an obviousness rejection, then the Examiner should have cited 35 USC §103(a) because 35 USC §102(e) relates only to anticipation.

With regard to in '855 to Buncke, the Examiner stated that the "figures show the proximal end of the needle [*sic*, is] about the same diameter of the suture".

Also, the Examiner stated that lines 13 - 21 of col. 7 of '911 to Granger et al. disclose "it was known to attach sutures of equal diameter to the suturing needle" and Fig. 12 of '911 to Granger et al. shows "the diameter of the needle shank portion 12 is smaller than the diameter of the suture."

Additionally, the Examiner stated that applicants' "claimed needle diameter could be the diameter of the needle at the sharpened tip, which would be smaller in diameter than the suture material." In connection therewith, applicants respectfully point out, as can be clearly seen in their Figures 13A, 13B, 13C, and 13D as filed, the diameter of the needle is clearly designated as the thickest part of the needle, and note that the rejected independent claims have been amended to indicate that the needle diameter is "at the needle's thickest part".

***Rejection of Claims 1, 2, 5 - 8, 10 - 13, 15, 16, 32, and 33 for anticipation, or in the alternative, obviousness over '855 to Buncke (in view of '911 to Granger et al.).***

As noted above, applicants once again respectfully remind the Examiner that, as specifically stated in paragraph 0181 of applicants' specification:

As is well known in the art, needle diameter for surgical needles used with conventional (i.e., unbarbed) sutures is considered unimportant, and often very thick surgical needles are used with thin conventional sutures such that the ratio of surgical needle diameter to conventional suture diameter is 4:1 or even higher, such as 4.43:1.

Also, applicants already noted above that '911 to Granger et al. shows an apparatus for attaching conventional sutures to surgical needles and thus applicants cited



'911 to Granger et al. as mere background for illustrating various ways of attaching surgical needles to sutures. Specifically, this reference does not have any disclosure whatsoever regarding barbed sutures, and hence, cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

In paragraph 7 of applicants' specification, applicants cited '855 to Buncke as mere background in that it is one of several references that show various barbed sutures attached to various surgical needles. However, '855 to Buncke does not at all address surgical needle diameter. Thus, this reference does not teach or suggest a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

Applicants again respectfully point out, as the Examiner should be aware, for a reference to be a reference under any paragraph of section 102, that reference, *by itself*, must teach each and every element of the claimed invention. That is not achieved by U.S. Patent No. 5,931,855 to Buncke by itself.

Furthermore, U.S. Patent No. 5,931,855 to Buncke and U.S. Patent No. 5,123,911 to Granger et al., in any combination whatsoever, do not suggest such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter. Moreover, since '911 to Granger et al. is silent vis-à-vis barbed sutures, applicants respectfully submit that there is no motivation to combine '911 to Granger et al. with '855 to Buncke. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Accordingly, with regard to claims 1, 2, 5 - 8, 10 - 13, 15, 32, and 33, the Examiner is respectfully requested to withdraw the rejection for anticipation over U.S. Patent No. 5,931,855 to Buncke and the rejection for obviousness over U.S. Patent No. 5,931,855 to Buncke in view of U.S. Patent No. 5,123,911 to Granger et al.

***Rejection of Claims 23 - 31 for anticipation, or in the alternative, obviousness over '855 to Buncke (in view of '911 to Granger et al.).***

Incorporated here by reference are the comments noted above, with regard to the limitations for the barbs recited in original claim 23 being incorporated by reference into dependent claims 24 – 31.

As mentioned above, '855 to Buncke was cited by applicants for background on various barbed sutures attached to various surgical needles. This reference does not at all address surgical needle diameter, and thus, does not teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter, and where the barbs have the various limitations as set out in claim 23.

As noted above, applicants respectfully reiterate that, as the Examiner should be aware, for a reference to be a reference under any paragraph of section 102, that reference, *by itself*, must teach each and every element of the claimed invention. That is not achieved by U.S. Patent No. 5,931,855 to Buncke by itself.

As also stated above, applicants cited '911 to Granger et al. as mere background for illustrating attachment of sutures to surgical needles. Specifically, '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, but rather involves an apparatus for attaching conventional sutures to surgical needles. Thus, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter, and where the barbs have the various limitations as set out in claim 23.

Consequently, U.S. Patent No. 5,931,855 to Buncke and U.S. Patent No. 5,123,911 to Granger et al., in any combination whatsoever, do not suggest such a ratio and the various limitations on the barbs as set out in claim 23. Moreover, since '911 to Granger et al. is silent vis-à-vis barbed sutures, applicants respectfully submit that there is no motivation to combine '911 to Granger et al. with '855 to Buncke. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection,

the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Accordingly for claims 23 - 31, the Examiner is respectfully requested to withdraw both the rejection for anticipation with regard to U.S. Patent No. 5,931,855 to Buncke and the rejection for obviousness with regard to U.S. Patent No. 5,931,855 to Buncke in view of U.S. Patent No. 5,123,911 to Granger et al.

***IV. Discussion of rejection of claims 1, 2, 5 - 7, 12, 13, 15, and 23 - 33 and 36 under 35 USC §103(a) as being obvious over U.S. Patent No. 3,123,077 to Alcamo in view of U.S. Patent No. 5,123,911 to Granger et al.***

The Examiner stated that '077 to Alcamo shows "a barbed suture having overlapping, spirally arranged, irregularly or regularly spaced [*sic*, barbs] about the suture". Also, the Examiner stated that lines 13 - 21 of col. 7 of '911 to Granger et al. disclose "that it was known to attach sutures of equal diameter to the suturing needle" and Fig. 12 of '911 to Granger et al. shows "the needle shank portion 12 is smaller than the diameter of the suture".

***Rejection of Claims 1, 2, 5 - 7, 12, 13, 15, 32, 33, and 36 for obviousness over '077 to Alcamo in view of '911 to Granger et al.***

As noted above, applicants cited '911 to Granger et al. as mere background for illustrating an apparatus for attaching conventional sutures to surgical needles. Since '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

With respect to '077 to Alcamo, applicants note that this reference is silent regarding surgical needles. Thus, this reference cannot possibly address surgical needle diameter. Therefore, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

Hence, U.S. Patent No. 3,123,077 to Alcamo and U.S. Patent No. 5,123,911 to Granger et al., in any combination whatsoever, do not suggest that such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter. Moreover, since '077 to Alcamo is silent vis-à-vis surgical needles and '911 to Granger et al. is silent vis-à-vis barbed sutures, applicants respectfully submit that there is no motivation to combine them. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 1, 2, 5 - 7, 12, 13, 15, 32, 33, and 36 over U.S. Patent No. 3,123,077 to Alcamo in view of U.S. Patent No. 5,123,911 to Granger et al.

***Rejection of Claims 23 – 31 for obviousness over '077 to Alcamo in view of '911 to Granger et al.***

Incorporated here by reference are the comments noted above, with regard to the limitations for the barbs recited in original claim 23 being incorporated by reference into dependent claims 24 – 31.

As mentioned above, '911 to Granger et al. is not relevant to barbed sutures, and applicants cited '911 to Granger et al. as mere background for illustrating an apparatus for attaching conventional sutures to surgical needles. Specifically, '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, and thus, cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle

combination with a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter, and where the barbs have the various limitations as set out in claim 23.

As also mentioned above, '077 to Alcamo is silent regarding surgical needles. Thus, '077 to Alcamo cannot possibly address surgical needle diameter. Therefore, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter, and where the barbs have the various limitations as set out in claim 23.

Hence, U.S. Patent No. 3,123,077 to Alcamo and U.S. Patent No. 5,123,911 to Granger et al., in any combination whatsoever, do not teach or suggest such a ratio and the various limitations on the barbs as set out in claim 23. Moreover, since '077 to Alcamo is silent vis-à-vis surgical needles and '911 to Granger et al. is silent vis-à-vis barbed sutures, applicants respectfully submit that there is no motivation to combine them. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 23 - 31 over U.S. Patent No. 3,123,077 to Alcamo in view of U.S. Patent No. 5,123,911 to Granger et al.

***V. Discussion of rejection of claims 8 - 11 under 35 USC §103(a) as being obvious over U.S. Patent No. 3,123,077 to Alcamo in view of U.S. Patent No. 5,123,911 to Granger et al., and further in view of U.S. Patent No. 6,599,310 to Leung et al.***

The Examiner stated that '077 to Alcamo as modified by '911 to Granger et al. "makes obvious the invention as claimed with the exception of the suture material" and that '310 to Leung et al. "discloses the claimed suture material."

Incorporated here by reference are the comments noted above, regarding that under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

At the time that the presently claimed invention was made, it and '310 to Leung et al. were owned by and also subject to an obligation of assignment to the same person, Quill Medical, Inc.

Accordingly, the Examiner is respectfully requested to remove the obviousness rejection over '077 to Alcamo in view of '911 to Granger et al. and further in view of '310 Leung et al.

Hence, remaining is only the rejection for obviousness solely based on '077 to Alcamo in view of '911 to Granger et al.

As noted above, '077 to Alcamo is silent regarding surgical needles. Thus, '077 to Alcamo cannot possibly address surgical needle diameter. Therefore, this reference cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

As also noted above, '911 to Granger et al. is not relevant to barbed sutures, and applicants cited '911 to Granger et al. as mere background for illustrating an apparatus for attaching conventional sutures to surgical needles. Specifically, '911 to Granger et al. does not have any disclosure whatsoever regarding barbed sutures, and thus, cannot possibly teach or suggest anything whatsoever regarding a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture diameter.

Hence, '077 to Alcamo and '911 to Granger et al., in any combination whatsoever, do not teach or suggest a barbed suture/surgical needle combination with such a ratio of about 3:1 or less for the surgical needle diameter to barbed suture

diameter. Moreover, since '077 to Alcamo is silent vis-à-vis surgical needles and '911 to Granger et al. is silent vis-à-vis barbed sutures, applicants respectfully submit that there is no motivation to combine them. Applicants respectfully note that, as the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 8 - 11 with regard to U.S. Patent No. 3,123,077 to Alcamo in view of U.S. Patent No. 5,123,911 to Granger et al.

***VI. Discussion of rejection of claims 3 and 4 under 35 USC §103(a) as being obvious.***

***Rejection of claims 3 and 4 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,599,310 to Leung et al. or U.S. Published Patent Application No. 2004/0030354 to Leung et al., in view of U.S. Patent No. 5,123,911 to Granger et al., as applied to the claims above, and further in view of U.S. Patent No. 5,258,013 to Granger et al.***

The Examiner stated that '310 to Leung et al. (or '354 to Leung et al.) as modified by '911 to Granger et al., "makes obvious the invention as claimed with the exception of the coating on the needle" and that '013 to Granger et al. "discloses that it was known to place a coating of silicone on a surgical needle" and that it "would have been obvious to have placed a silicone coating on the needle of Leung, as this facilitates the passage of the needle through the tissue."

Applicants respectfully reiterate the comments above that under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject

matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

At the time that the presently claimed invention was made, it and both of '310 to Leung et al. and '354 Leung et al., were owned by and also subject to an obligation of assignment to the same person, Quill Medical, Inc.

Accordingly, the Examiner is respectfully requested to remove the obviousness rejection based on one or both of Leung et al. in view of '911 to Granger et al. and '013 to Granger et al.

Hence, remaining is only the rejection for obviousness solely in view of '911 to Granger et al. and/or '013 to Granger et al.

With regard to '013 to Granger et al., the Examiner is correct that this reference discloses that it was known to place a coating of silicone on a surgical needle. However, '013 to Granger is silent with regard to any kind of sutures, whether conventional or barbed.

A polymeric coating (dependent claim 3), or in particular a silicone polymeric coating (dependent claim 4), on a surgical needle must be considered together with the specifically claimed ratio of the surgical needle diameter to the barbed suture diameter of about 3:1 or less.

Nowhere in '911 to Granger et al. or '013 to Granger et al., either alone or in combination, are these requirements taught or suggested. Moreover, since '911 to Granger et al. is silent vis-à-vis barbed sutures and '013 to Granger is silent with regard to any kind of sutures, whether conventional or barbed, applicants respectfully submit that there is no motivation to combine them. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Thus, '911 to Granger et al. and '013 to Granger et al., in any combination whatsoever, do not teach or suggest the specifically claimed ratio of the surgical needle diameter to the barbed suture diameter of about 3:1 or less, together with a polymeric



coating (dependent claim 3), or in particular a silicone polymeric coating (dependent claim 4), on a surgical needle.

Accordingly, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 3 and 4 under 35 USC §103(a) with regard to U.S. Patent No. 5,123,911 to Granger et al. and U.S. Patent No. 5,258,013 to Granger et al.

***Rejection of claims 3 and 4 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,123,911 to Granger et al., in view of U.S. Patent No. 3,123,077 to Alcamo, as applied to the claims above, and further in view of U.S. Patent No. 5,258,013 to Granger et al.***

The Examiner stated that '911 to Granger et al. as modified by '077 to Alcamo "makes obvious the invention as claimed with the exception of the coating on the needle" and that '013 to Granger et al. "discloses that it was known to place a coating of silicone on a surgical needle" and that it "would have been obvious to have placed a silicone coating on the needle of Leung, as this facilitates the passage of the needle through the tissue."

Applicants respectfully reiterate that '911 to Granger et al. shows various surgical needles attached to conventional sutures but is silent regarding barbed sutures; '077 to Alcamo is silent regarding surgical needles; and '013 to Granger et al. shows coating silicone onto a surgical needle but is silent regarding any kind of sutures, whether barbed or conventional.

Accordingly, no combination whatsoever of these three references can teach or suggest a particular ratio of about 3:1 or less for the surgical needle diameter to the barbed suture diameter.

As applicants noted above, a polymeric coating (claim 3), or in particular a silicone polymeric coating (claim 4), on a surgical needle must be considered together with ratio of about 3:1 or less for the surgical needle diameter to the barbed suture diameter.

Thus, U.S. Patent No. 5,123,911 to Granger et al., U.S. Patent No. 3,123,077 to Alcamo, and U.S. Patent No. 5,258,013 to Granger et al., in any combination whatsoever, do not suggest such a ratio of about 3:1 or less for the surgical needle diameter to the barbed suture diameter. Moreover, since '911 to Granger et al. is silent vis-à-vis barbed sutures and '077 to Alcamo is silent vis-à-vis surgical needles and '013 to Granger et al. is silent vis-à-vis is silent vis-à-vis any kind of sutures whether conventional or barbed, applicants respectfully submit that there is no motivation to combine them. As the Examiner should be well aware, for references to be properly combined in an obviousness rejection, the motivation for combining the references must be in the references themselves, and not derived from hindsight obtained by the Examiner from reading applicants' specification.

Hence, the Examiner is respectfully requested to withdraw the rejection for obviousness of claims 3 and 4 under 35 USC §103(a) with regard to U.S. Patent No. 5,123,911 to Granger et al., U.S. Patent No. 3,123,077 to Alcamo, and U.S. Patent No. 5,258,013 to Granger et al.

***VII. Discussion of allowance of selected claims.***

The Examiner indicated that "Claims 17 - 22, 43 [*sic*, 34], and 35 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claims and any intervening claims."

As noted above, each of originally dependent claims 17, 18, and 21 (each of which depended back to original dependent claim 12, which depended back to original independent claim 1) has been rewritten to be an independent claim, incorporating all of the limitations of original claims 12 and 1.

Each of dependent claims 19 and 20 depends back to now independent claim 18, and thus, incorporates the limitations thereof. Dependent claim 22 depends back to now independent claim 21, and thus, incorporates the limitations thereof. Thus, none of

claims 19, 20, and 22 has been amended. Each of claims 34 and 35 was already an independent claim.

Therefore, applicants respectfully submit that all of claims 17 - 22, 34, and 35 are in condition for allowance.

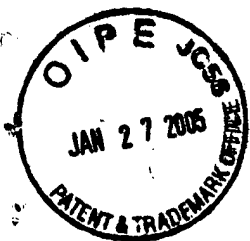
## CONCLUSIONS

Applicants respectfully submit that in view of the above comments regarding drawing sheet 7 and the submission of additional drawing sheets 9, 10, and 11, and new paragraphs 0179.1 through 0179.12 discussing sheets 9, 10, and 11, the Examiner is respectfully requested to withdraw the objections to the drawings. Additionally, the Examiner is respectfully requested to enter additional sheets 9, 10, and 11, and new paragraphs 0179.1 through 0179.12 that discuss these sheets.

Also, applicants respectfully submit that in view of the above claim amendments, all claims are allowable, and the Examiner is respectfully requested to withdraw the various rejections under 35 USC §102(e) and under 35 USC §103(a). Also, applicants respectfully submit that claims 17 - 22, 34, and 35, to which the Examiner objected, are in condition for allowance. Additionally, applicants respectfully submit that new method claims 37 - 54, which correspond respectively to original product claims 1 - 16, 32, and 33, are allowable based on the above arguments.

Accordingly, the Examiner is respectfully requested to allow all claims. Hence, applicants respectfully submit that the case is in condition for allowance and early allowance is earnestly solicited.

If the Examiner should have any questions of a minor nature after reading the above, the Examiner is respectfully requested to telephone the undersigned in order to attend to any such minor issues and obviate the issuance of another Official Action.

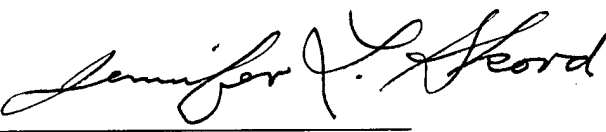


## DEPOSIT ACCOUNT

Although enclosed is a check in the amount of \$3120.00 (\$1020.00 for the Petition for a 3-month extension, and \$1200.00 for the presentation of 6 additional independent claims @ \$200.00, and \$900.00 for the presentation of 18 additional claims @ \$50.00), and thus, it is believed that no fee is due, the Commissioner is authorized to charge any deficiencies of payment associated with this Communication, or to credit any overpayment, to **Deposit Account No. 13-4365**.

Date: January 27, 2005

Respectfully submitted,

By: 

Jennifer L. Skord  
Reg. No. 30,687

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Encls.: Petition for 3-month extension of time  
\$3120.00 check (LARGE entity status -- \$1020.00 fee for Petition for 3-month extension and \$1200.00 fee for 6 additional independent claims and \$900.00 fee for 18 additional claims)  
Additional sheets 9, 10, and 11 of drawings